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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/088,639	03/20/2002	Thomas Brodin	003300-920	7152

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EXAMINER	
HELMS, LARRY RONALD	
ART UNIT	**PAPER NUMBER**
1642	

DATE MAILED: 06/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/088,639	BRODIN ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-57* is/are pending in the application.

4a) Of the above claim(s) *17-33,35,36 and 38-57* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16, 34, 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-3, 5-16 have been amended.

2. Claims 17-33, 35-36, 38-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions. Applicant timely traversed the restriction (election) requirement in the reply filed on 9/15/04.

3. Claims 1-16, 34, 37 are under examination.

4. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

Rejections Withdrawn

5. The rejection of claim 2 paragraph 6b in the previous Office Action under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of arguments.

6. The rejection of claims 1-6, 16 under 35 U.S.C. ' 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments to the claims.

Response to Arguments

7. The rejection of claims 1-16, 34, 37 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for paragraphs 6a, 6c-g in the previous Office Action is maintained.

The response filed 4/18/05 has been carefully considered but is deemed not to be persuasive. The response states that the dictionary defined "derivative" and derivatization is disclosed in the specification (see page 13-14 of response). In response to this argument, it is still unclear how the molecules are derived. While the dictionary definition states that the term is any compound that may be formed from another to which it is structurally related, this definition does not indicate how or what the derivative is.

The response further states that the phrase "similar unique binding properties" is clear and is defined to be those that bind to the target structure displayed in or on the cells of human gastrointestinal tumor and in a subpopulation of normal (see page 14 of response). In response to this argument, it is still unclear what the phrase means because the phase can mean a myriad of things such as similar affinity, avidity, binding to the same antigen, or some other "binding property".

The response further states that "sequences have an identity of at least 84%" is clear and is the phrase means identity to sequence of human origin (see page 15 of response). In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

In response to this the claims do not state this and are indefinite.

The response further states that the term "changed" is clear and means the antibody has been changed genetically (see page 15 of response). In response to this argument, the claims do not recite that the antibody has been changed genetically and as such the rejection is maintained. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The response further states that the phrase "other binding structures" is clear and well known (see page 15 of response). In response to this argument the claim is still indefinite.

The response further states that the phrase "subpopulation of normal human gastrointestinal epithelial cells" is definite and cites the specification for disclosing A3 binds to some but not all cells as indicated in the Table 1 and page 21 of the specification and thus the subpopulation would be understood (see page 15-16 of the response). In response to this argument, the claims do not recite this subpopulation and as such is unclear. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

8. The rejection of claims 34, 37 under 35 U.S.C. 112, first paragraph, is maintained.

The response filed 4/18/05 has been carefully considered but is deemed not to be persuasive. The response states that applicants have enclosed an article showing therapeutic effect of an antibody superantigen conjugates in tumor therapy (see page 17 of response). In response to this argument, the claims do not require any superantigen conjugates and therefore the argument is irrelevant. In addition the response did not address the claim to a vaccine or any of the cited art in the 112 first rejection or the enablement of 84% identity in the CDRs

9. The rejection of claims 1, 2, 7, 8, 9, 34, 37 under 35 U.S.C. 102(b) as being anticipated by Fernsten et al (Cancer Research 51:926-934, 1991, PTO-892, 5/20/04) is maintained.

The response filed 4/18/05 has been carefully considered but is deemed not to be persuasive. The response states the presently claimed antibody has a unique reactivity pattern which supports the assertion that it is completely different to that of Fernsten and Fernsten antigen is 48 kDa and the instant antigen is 80-160 kDa (see pages 18-19 of response). In response to this argument, the claims only require a binding structure with similar unique binding properties of binding to human gastrointestinal tumor cells and in a subpopulation of normal gastrointestinal epi cells. There is nothing in the claim for what the subpopulations is or the MW of the antigen or

what a similar unique binding property is. As indicated in the 112 second the claims are indefinite. Thus, the art meets the limitations because the art teaches an antibody that binds human gastrointestinal epithelial tumor cells and normal human gastrointestinal epithelial cells (see abstract and page 928) and the antibody is conjugated to horseradish peroxidase or 125I and compositions comprising such (see pages 927 and 928). Because of the indefinite nature of the claims the antibody of Fernsten et al meets the limitations if the claims because the antigen is in human gastrointestinal epithelial tumor cells and normal human gastrointestinal epithelial cells because the normal cells were cell lines and normal adjacent tissue which would be a subpopulation.

With regard to claim 2, which recites the antibody which is phage selected, the method in which the antibodies were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113.

10. The rejection of claims 1-2, 7, 16, 34, 37 under 35 U.S.C. 102(b) as being anticipated by Quaranta et al (US Patent 5,320,942, issued 6/1994) is maintained.

The response filed 4/18/05 has been carefully considered but is deemed not to be persuasive. The response states the antibodies of Quaranta uses different methodologies to produce the antibodies and thus they are different and different epitopes of alpha4beta6 integrin are recognized by the antibodies of Quartanta compared to those of the instant invention (see page 19 of response). In response to this argument, the method in which the antibodies were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113.

11. The rejection of claims 1-2, 4-15, 34, 37 under 35 U.S.C. 103(a) as being unpatentable over Fernsten et al (Cancer Research 51:926-934, 1991) as applied to claims 1-2, 7-9, 34, 37 above, and further in view of Queen et al (US Patent 6,180,370, filed 6/1995) is maintained.

The response filed 4/18/05 has been carefully considered but is deemed not to be persuasive. The response argues the same for the Fernsten reference as in the 102(b) above and that Queen and Fernsten in combination doe not teach the claimed antibodies (see page 21 of response). In response to this the rebuttal above for Fersten is applied and in combination Fersten and Queen meet the limitations in the claims.

12. The rejection of claims 1-2, 4-16, 34, 37 under 35 U.S.C. 103(a) as being unpatentable over Quaranta et al (US Patent 5,320,942) as applied to claims 1-2, 7, 16, 34, 37 above, and further in view of Queen et al (US Patent 6,180,370, filed 6/1995) is maintained.

The response filed 4/18/05 has been carefully considered but is deemed not to be persuasive. The response argues the same for the Quartanta reference as in the 102(b) above and that Queen and Quartanta in combination doe not teach the claimed antibodies (see page 21 of response). In response to this the rebuttal above for Quartanta is applied and in combination Quartanta and Queen meet the limitations in the claims.

13. The rejection of claims 1-9, 11, 14-16, 34, 37 under 35 U.S.C. 103(a) as being unpatentable over Quaranta et al (US Patent 5,320,942) as applied to claims 1-2, 7, 16, 34, 37 above, and further in view of Anderson et al (US Patent 6,113,898 , filed 6/1995) is maintained.

The response filed 4/18/05 has been carefully considered but is deemed not to be persuasive. The response argues Anderson does not disclose or suggest how to identify the binding structures of the present invention or how to screen for binders (see page 23 of response). In response to this argument, it is unclear what this argument

has to do with the rejection because the claims do not require such screening. The response then argues unexpected results but does not show any results and in addition the claims are not commensurate in scope with the asserted unexpected results because the claims do not require low reactivity with normal lung and kidney as claimed in page 23 of the response.

Conclusion

14. No claim is allowed.

15. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 6:30 am to 4:00 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

17. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Larry R. Helms

571-272-0832

LARRY R. HELMS, PH.D
PRIMARY EXAMINER